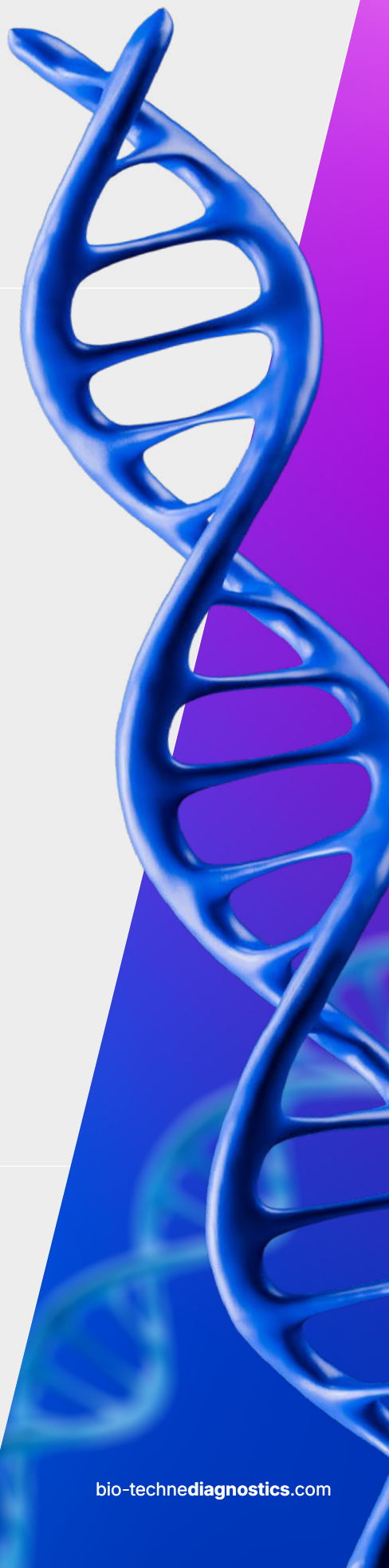
bio-techne diagnostics™



AmplideX® Nanopore Carrier Plus Kit

Streamlining Carrier Screening Insights, *Even for the Most Challenging Genes*

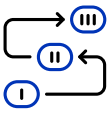
A Long-Range PCR and Long-Read Sequencing Solution for Carrier Screening Research

The AmplideX® Nanopore Carrier Plus Kit interrogates fifteen genes that contribute to high at-risk couple rates in carrier screening.

The design utilizes five mixes across the fifteen genes with modularity to allow any combination of testing.

With a single, flexible workflow designed to consolidate existing assays and methods, Carrier Plus can be used as a primary genetic analysis method or to complement existing NGS workflows for large panels. The use of long-read sequencing provides additional insights and reduces the need for reflex testing compared to traditional methods. The AmplideX One Reporter software further simplifies data analysis and reporting for a seamless, streamlined workflow.

Fifteen Genes, Thirteen High-Prevalence Carrier Screening Conditions, One Workflow



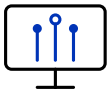
Consolidated Workflow

Single, flexible workflow designed to consolidate existing assays and methods (e.g., SNV and CNV detection for both *HBA1/2* and *HBB* in a single reaction).



Greater Insights

The use of long-read sequencing provides additional insights compared to existing methods (e.g. AGG interruptions in *FMR1*), reducing the need for reflex testing.



Integrated Data Analysis

The AmplideX One Reporter software further simplifies data analysis and reporting by providing automated quality control and visual outputs to simplify complex genotype interpretations.

Two and a Half Days From Extracted DNA to Results Across Multiple Samples and Genes

	1 Enrichment	2 Quantification & Pooling	3 Library Prep	4 Sequencing	5 Data Analysis	Total
	a. Gene-Specific PCR b. Bead Purification c. Barcoding PCR	a. Quantification of Individual PCR Products and Within-Mix Pooling b. Bead Purification of Pooled Mixes c. Quantification of Pooled Mixes and Between-Mix Pooling	a. End Repair and dA-Tailing b. Adapter Ligation c. Library Quantification & Formulation	• Flow Cell Preparation and Loading		
Hands-On Time (Hrs:Mins)	1:25	1:15	1:20	0:10	0:05	4:15
Instrument Time (Hrs:Mins)	5:00	0:00	0:00	9:00	1:10	15:10

Hands-on time and instrument time for AmplideX Nanopore Carrier Plus Kit (a 24 sample run across Mixes A, B, and C).

Kit Configuration: Fifteen Genes Across Five Mixes

Genes Included

Mix A	Mix B	Mix C	Mix D	Mix E*
SMN1	*FMR1*	*HBA1*	*CYP21A2*	*FXN*
SMN2	*AFF2**	*HBA2*	*TNXB*	*ARX*
CFTR		*HBB*	*F8* Intron Inv.	*RPGR*
			GBA	

*These genes will be part of new features of the Carrier Plus Kit. Final product features and characteristics to be determined.

Excellent Performance Across All Genes in the Assay

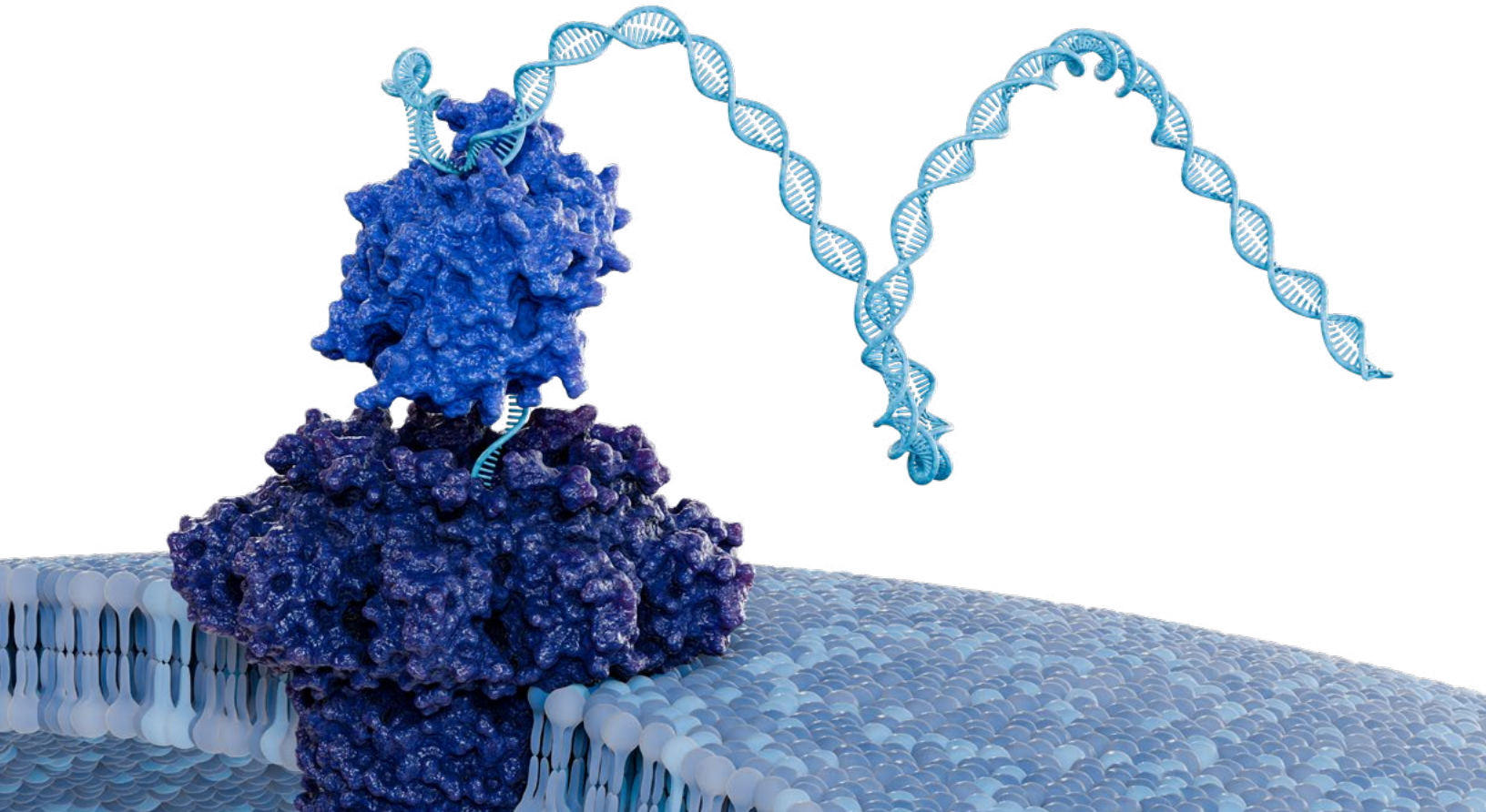
Gene	Variant Types	N Measurements	Sample Genotype Percent Agreement
CFTR	SNV, indel, CNV (LED), STR (PolyT/TG)	276	99.3%
SMN1	SNV, indel, CNV	270	97.4%†
SMN2	SNV, indel, CNV	270	97.4%
FMR1	STR (CGG), AGG interrupts	212	99.5%
HBA1/2	SNV, indel, CNV, SV	175	100%
HBB	SNV, indel, CNV	175	100%
F8	SV (intron 1 and intron 22 inversions)	180	100%
GBA	SNV, indel, CNV, SV	178	100%
CYP21A2	SNV, indel, CNV, SV	167	100%
AFF2	STR (CCG), SNV	TBD	TBD
FXN	STR (GAA), interrupts	TBD	TBD
ARX	STR (GCN), SNV	TBD	TBD
RPGR	SNV, indel	TBD	TBD

Genotype agreement with orthogonal methods from method comparison and within lab precision studies of the design verification testing (Source: Internal data on file). For *SMN1/SMN2*, this represents copy number agreement (0, 1, 2, ≥3). For other gene targets, this represents agreement for number of affected alleles (0, 1, ≥2).

†Agreement was 100% at 0 and 1 copies.

Note: Five samples with known TNXB structural variants or SNVs were 100% concordant.

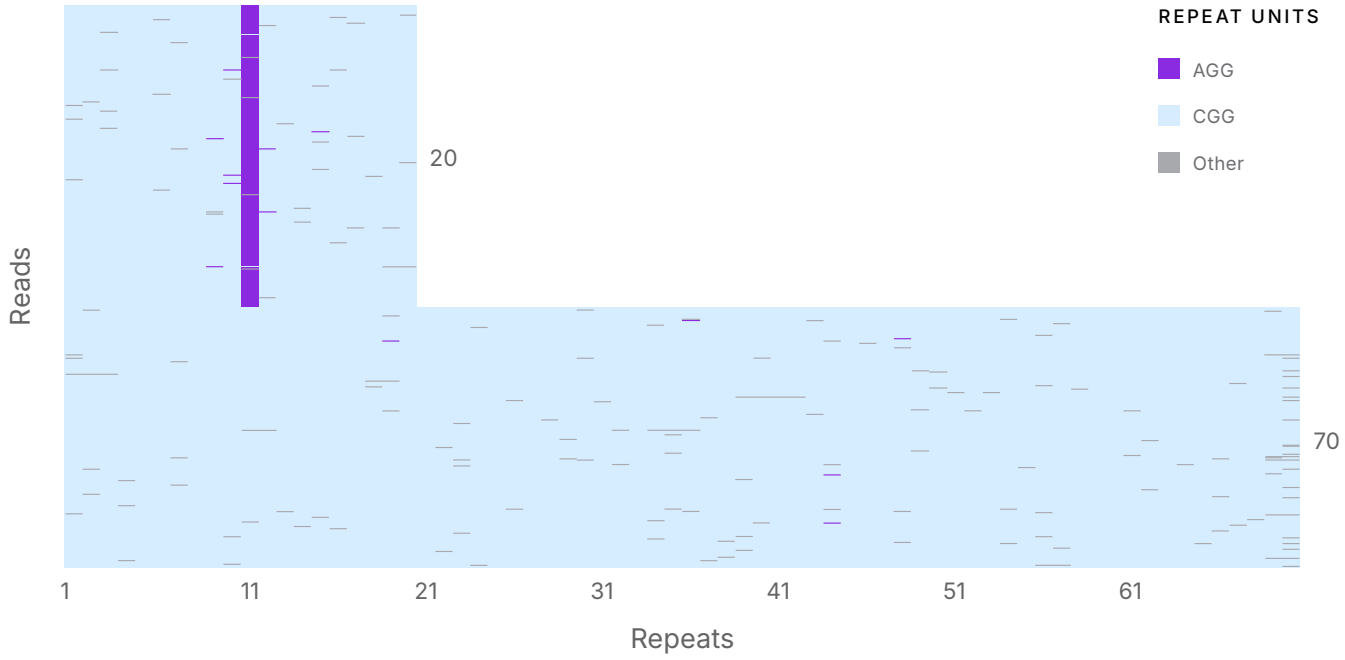
SNV: Single Nucleotide Variant; LED: Large Exon Deletion; PA: polyalanine; STR: Short Tandem Repeats; CNV: Copy Number Variation; SV: Structural Variant



Multiple Gene/Variant Level Visualizations Provide Meaningful Insights

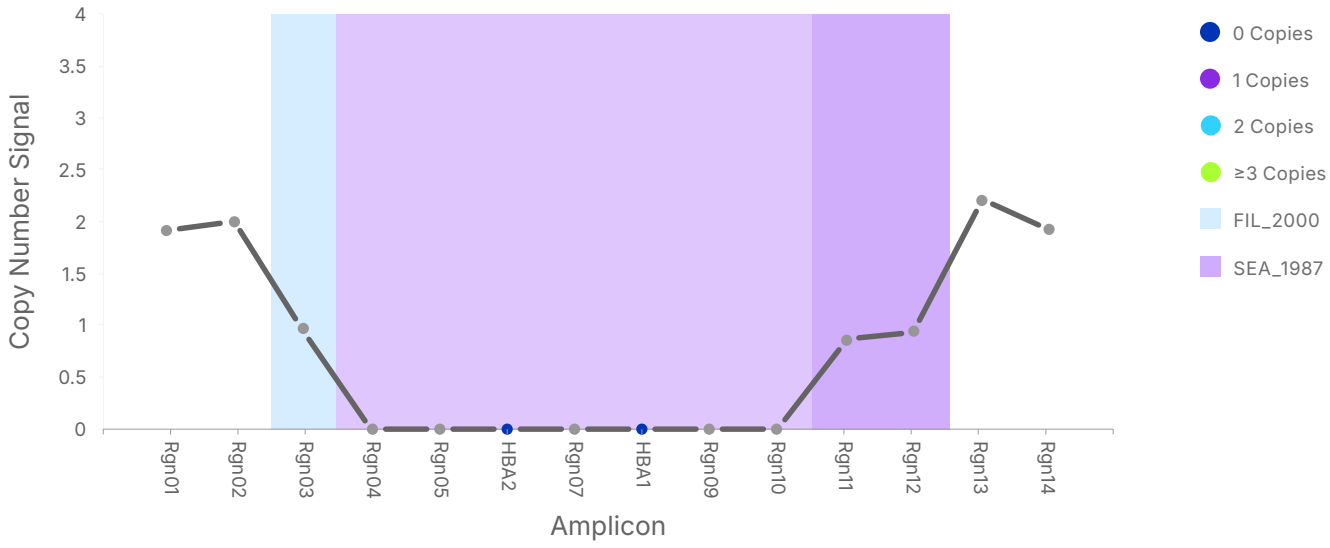
Examples of Visual Outputs for Various Gene/Mixes:

Pre-Mutation (PM) Sample with no AGG on PM Allele



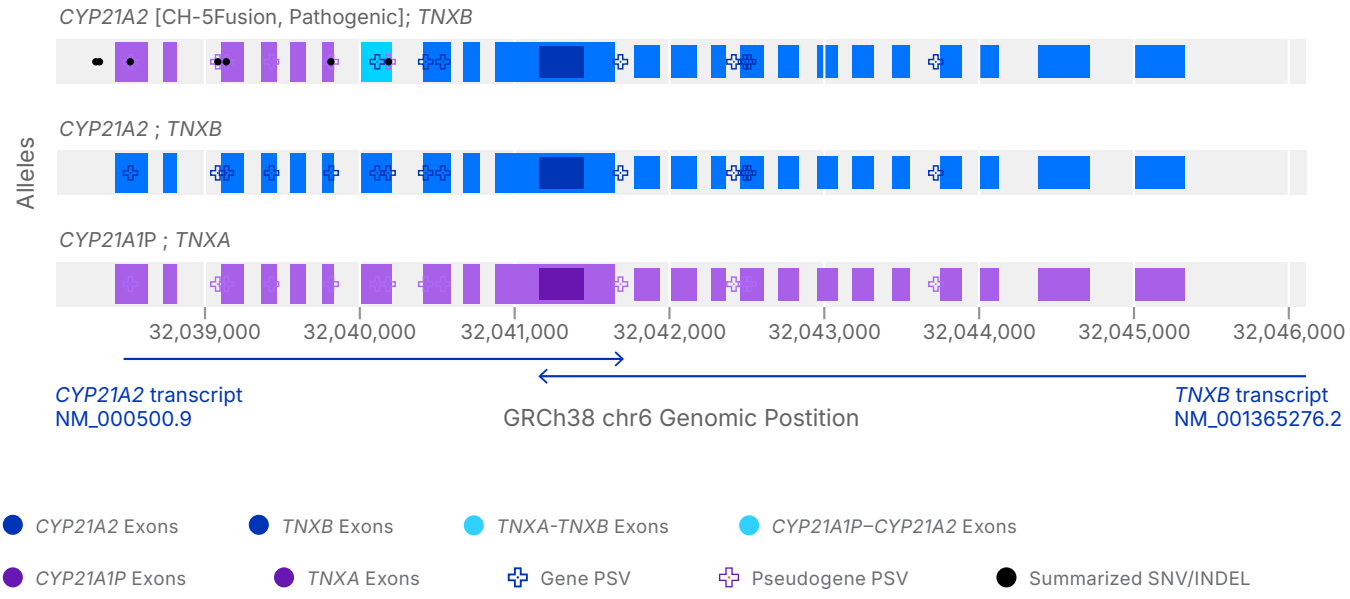
FMR1 output provides CGG sizing and AGG phase and location for each allele.

NA10797—Compound HET FIL/SEA Sample



HBA1/2 fold change plot provides accurate copy number and identification of major deletion genotypes.

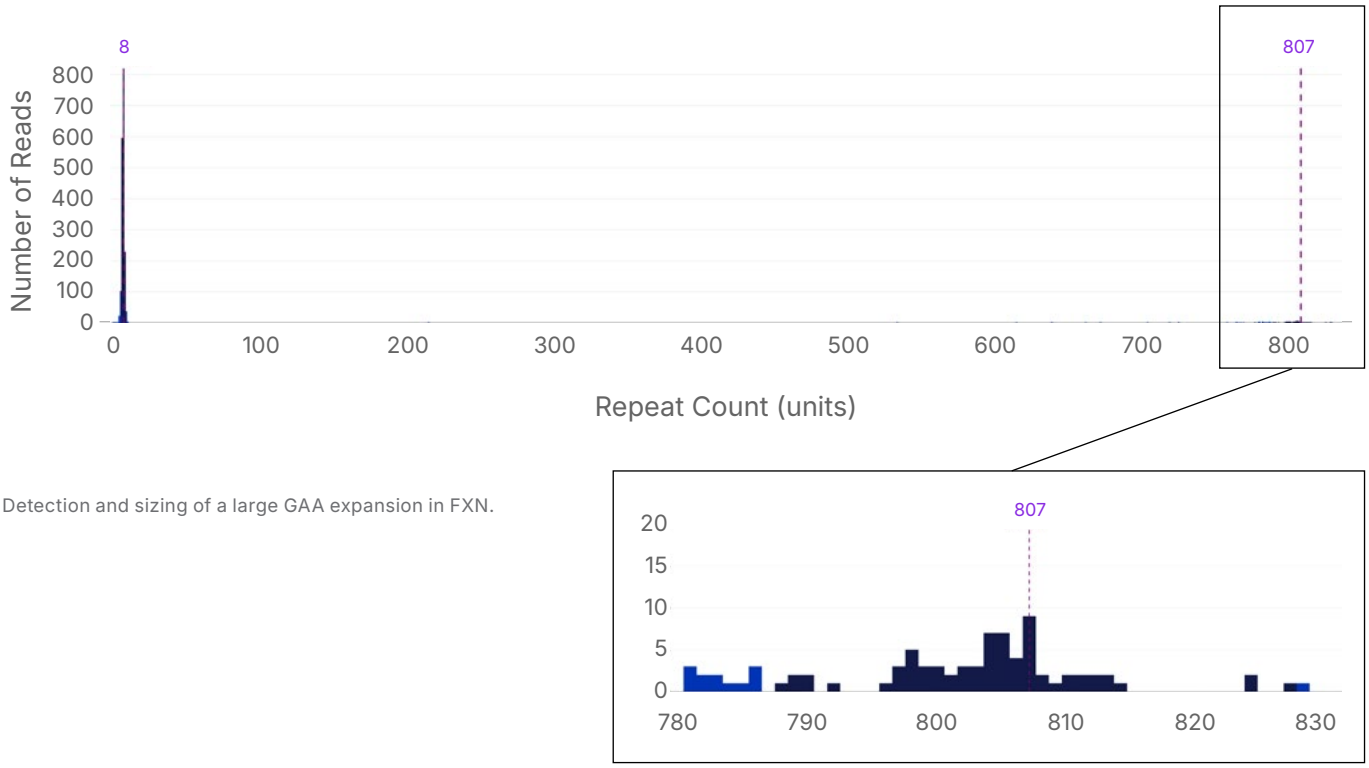
NA14733—2 Copies of *CYP21A2*, One Which is a CH-5 Fusion



Resolution of *CYP21A2/TNXB* gene/pseudogene structure down to each exon provides clear visualization of the various changes in this region including phased SNVs.



NA16202 - Expanded Female Sample (8, 807)



Detection and sizing of a large GAA expansion in FXN.

Ordering Information

Part No.	Product	Number of Reactions
A00627	AmplideX Nanopore Carrier Plus Kit A	96
A01180	AmplideX Nanopore Carrier Plus Kit B*	96
A00629	AmplideX Nanopore Carrier Plus Kit C	96
A00630	AmplideX Nanopore Carrier Plus Kit D	96
A01181	AmplideX Nanopore Carrier Plus Kit E*	96

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For Research Use Only. Not for use in diagnostic procedures.
*Mix E targets and *AFF2* in Mix B are under development; performance characteristics and final product features to be determined.

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